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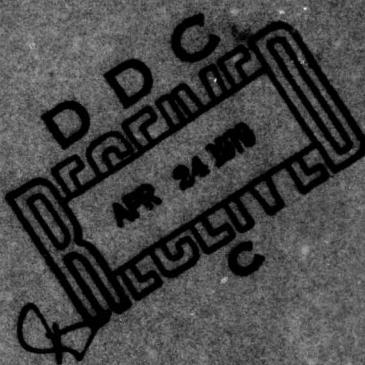
REPORT NUMBER 9

SURGICAL TOOTH IMPLANTS, COMBAT AND FIELD

Annual Report

Craig R. Hassler, Robert H. Downes, Gary L. Messing
and Orville E. Russell

December 1, 1978



Supported by

U. S. ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND
Fort Detrick, Frederick, Maryland 21701

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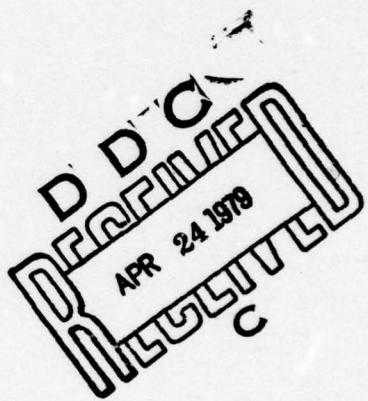
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Implants have been followed in the baboon colony for three years. "Success" continues to be at the same level as reported in the previous year. The "success" rate this year for roots ingrown and in function has been 92%. Failure of roots usually occurs during the initial 3-month ingrowth period. This ingrowth period is most crucial to the overall success of the implant. The three piece design as well as the wide variety of available sizes assists in minimizing loss during the ingrowth period. In the last year, failure rate during ingrowth has been 14%. Presently, 31 roots (24 in function) are being followed in baboons. The human implant study has been underway for six months. To date, seven patients have been implanted and are in the ingrowth period prior to reconstruction. The clinical course appears similar to the baboon, except ingrowth appears to be considerably slower.

It is intended that the animals and patients in this study be followed as long as possible so that the true long-term effects of such an implant system can be adequately evaluated.

FOREWORD

This study has been conducted at Battelle's Columbus laboratories utilizing the staff and resources of the Bioengineering/Health Sciences Section and the Ceramics Section. The clinical portion of this study has been conducted at The Ohio State University College of Dentistry.

This is the ninth annual report on progress under Contract No. DADA-17-69-C-9181, "Surgical Tooth Implants, Combat and Field". The principal investigator for this research was Dr. Craig R. Hassler. Ceramics research was directed by Dr. Gary L. Messing. The human studies have been under the direction of Dr. Robert H. Downes and have been conducted in the clinical facilities of the College of Dentistry. Clinical research was conducted under a protocol approved by The Ohio State University human subjects committee. Animal research, conducted at Battelle Columbus has followed the guidelines of the "Guide for Laboratory Animals Facility and Care" as promulgated by the Committee on the Guide for Laboratory Animal Resources, National Academy of Sciences, National Research Council.

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ABSTRACT

Long term implant studies of alumina tooth roots are being performed in both humans and baboons. The implants designed for this project are single root elliptical and rectangular designs with serrations arranged for maximal stress distribution of occlusal loads. The implant is of a three-piece design. Roots are produced by grinding bisque fired alumina stock on a computer controlled milling machine. This technique provides high quality, high strength, and design flexibility. A series of sixteen graded sizes of implants have been produced. Extensive quality assurance has been performed on the implants intended for human implant. Quality assurance procedures include: wet densities, radiography, visual inspection and mechanical testing of test bars. The quality of alumina root has consistently improved throughout this project.

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SURGICAL TOOTH IMPLANTS, COMBAT AND FIELD

by

Craig R. Hassler, Robert H. Downes, Gary L. Messing
and Orville E. Russell

BACKGROUND

In the last several years a new generation of dental implants have evolved. These devices are designed to be rigidly affixed by bone ingrowth and provide minimization of stress usually by serrations⁽¹⁻⁴⁾ or pores.^(5,6) Generally, these implants are designed as single free-standing prostheses. Several biocompatible materials have been utilized including plastics,⁽⁷⁾ metallics⁽⁶⁾ and ceramics.^(1,2,3,8-17) Our laboratory has been using alumina ceramics because of its biocompatibility. A combination of material, design and technique has evolved which appears promising in animals. Implant experience in baboons approaches 3 years of function. On the strength of the animal experiments, a clinical study has recently been undertaken. It is premature to talk about results for the clinical study.

The lower portion of our three-piece implants are produced from alumina (Figure 1). This portion has large serrations into which bone ingrowth has been demonstrated. Stress must be minimized until bone ingrowth is sufficient to allow the root to be put into function. This initial ingrowth period is most crucial to the ultimate fate of the implant. The three-piece design allows minimization of occlusal stresses on the implant to facilitate the ingrowth. Once the implant is stabilized by ingrowth, the large implant surface area at right angles to the axis of the implant is intended to minimize bone stresses below a level which would produce resorption of bone. The stresses which can produce remodeling bone have been quantified in this laboratory.⁽⁹⁾ This information is not specifically for alveolar bone. However, it serves as a guide in an area where no direct information is available. Our baboon data tend to validate this assumption.

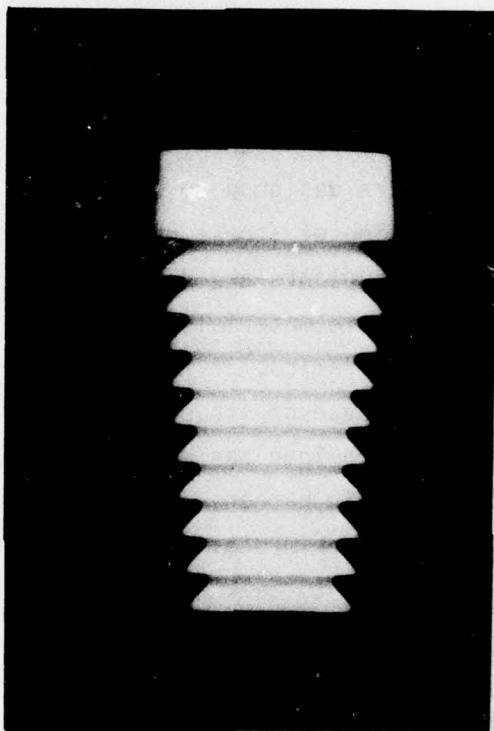


FIGURE 1. Al₂O₃ IMPLANT INTENDED FOR HUMAN USE

The above mentioned design parameters, unique to this design, are the serrations and three piece construction. They are the two major determinants for design success. A secondary design parameter which has proven useful is the use of a graded series of implants. This gradation allows optimal fit into the available site. Fifteen sizes have been produced for the clinical studies. Both rectangular and elliptical implants were used in baboons. The rectangular shape appears to provide a better initial fit into fresh extraction site in pre-molar and molar regions. Consequently, this design is being used exclusively in the clinical trials. The method of producing roots by contour grinding on a computer controlled milling machine has allowed for flexibility not only in size but in other design changes. In a research protocol, this ease of flexibility has been an asset and will continue to be our method of root manufacture.

The concept of providing adequate stress distribution area cannot be overemphasized. It appears to be fundamental to the apparent success of this implant at this time. The long term animal success is encouraging. Success for a similar or longer time span in humans is necessary to determine the true success of the implant.

METHODS

Ceramic Studies

Powder Processing

In the last year the powder used for the fabrication of alumina tooth root implants was changed from Alcoa's A-16SG to Reynold's RC-HP-DBM. This decision was based on a comparative study of the mechanical properties of flexure bars prepared from the two powders.

Chemically, the two powders are essentially identical with the Alcoa powder containing twice as much (.05 weight percent) MgO as is used in the Reynold's alumina. The MgO content is intentionally added as a grain growth inhibitor. Physically, the grain size (1.0 microns) of the Alcoa powder is twice that of the Reynold's powder (0.5 microns).

The mechanical tests were performed on a series of test bars prepared from the two powders at the same sintering conditions. Rods (3/8 x 3/8 x 4-1/2 in.) were isostatically pressed at 55 Kpsi from the two

powders and bisque fired for 2 hours at 2100 F (1149C). Flexure test bars were ground to have sintered dimensions of 0.125 x 0.250 x 1.50 in. and fired to final density at 3050 F (1677 C) for 2 hours. The fired densities were 98.9 percent and 98.75 percent of theoretical for the Alcoa and Reynolds powders, respectively. Samples prepared from the Alcoa powder gave an average flexural strength in 4-point loading of 43,730 psi and the Reynolds samples gave an average strength of 52,616 psi. From a statistical analysis the equivalent 3-point bending strengths are 53 Kpsi and 63.9 Kpsi for the Alcoa and Reynolds powders, respectively.

Using the Reynolds powder it was found that rod stock bisque fired at 2100 F for 2 hours was too hard for the established milling procedures and resulted in accelerated tool wear. From a series of sintering tests the bisque temperature was lowered to 2050 F to yield a sufficiently soft stock for the computer controlled milling operation. It was also found necessary to lower the final sintering temperature to eliminate exaggerated grain growth which is deleterious to the mechanical properties of the alumina samples. The lowering of the sintering temperature to 2800 F (1538 C) and the sintering time to 1 hour resulted in a finer average grain size (1-5 microns) than previously attained (10-15 microns). This reduction of average grain size and the elimination of exaggerated grain growth has resulted in better mechanical properties.

Fabrication of Tooth Roots

Tooth roots were fabricated by essentially the same process as used in previous years.^(2,9) The rectangular design (Figure 1) was chosen for the clinical study that is being conducted at the Ohio State College of Dentistry.

The various sizes of implants prepared are given in Table 1. The total number of roots produced was 70 with a rejection rate of 10%. With the present root design it was determined that the 6mm x 5mm and 7mm x 5mm roots could not be made with a 15mm serration length but could with a 12mm length. Alumina plug gauges were made for each of the sizes. The plug gauges were fabricated in the same manner as the roots except an alumina handle was ground at the top.

TABLE I. TOOTH ROOT SIZES (Millimeters)

Size	Size	Size	Size
6 x 5 x 12	8 x 6 x 15	9 x 9 x 15	10 x 10 x 15
6 x 6 x 12	8 x 8 x 15	10 x 7 x 15	11 x 8 x 15
7 x 5 x 12	9 x 7 x 15	10 x 8 x 15	11 x 9 x 15
7 x 6 x 15	9 x 8 x 15	10 x 9 x 15	11 x 10 x 15

The first two numbers are length and width of the implant. The third number is the length of the serrated portion of the implant.

Quality Assurance

Quality assurance procedures were performed on all tooth roots after final sintering. These procedures included: wet densities, radiography, visual inspection and mechanical testing of test bars sintered with the tooth roots.

- (1) Density - The density of every tooth root was determined by a simple water immersion technique. To enhance the wetting of the surface, a surfactant was added to the water. The average density for all of the tooth roots was 99.75% of theoretical and 93% of the tooth roots had densities of at least 99% of theoretical.
- (2) Strength - The flexure strength of the sintered alumina was determined in 4-point bending with a specially designed testing jig.(18) In all cases the tentative ASTM strength requirements of 58 Kpsi were exceeded. Details of the strength limiting flaws were also determined and have been characterized.(19)
- (3) Radiography - Radiography was used for the detection of flaws within the tooth roots. While large porous regions were detectable, known micro-flaws were not. Because of the translucency of this material, microcracks were detectable under a stereo-microscope.
- (4) Chemistry - The chemistry of the alumina powder has been given in an earlier part of this report. In the examination of fracture surfaces in the SEM, an EDAX scan was run to determine whether there were any contaminants at the fracture site. These results showed no detectable amounts of impurities either in the porous region or in the matrix.
- (5) Microstructure - A typical microstructure of the alumina is shown in Figure 2. This micrograph (4500X) shows essentially two important features. The smaller raised area results from uncrushed agglomerates in the as-received powder. It is this type of flaw which controls the strength of the alumina and can be as large as 100 μm . The microstructure of the adjacent area shows the grain size to vary from 1 to 3 μm .

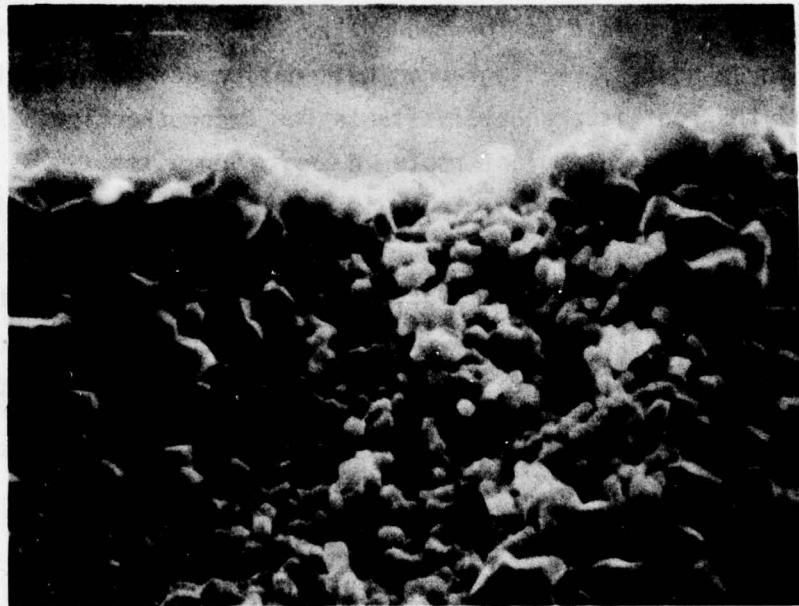


FIGURE 2. MICROGRAPH OF FIRED ALUMINA (4500X) THE SMALL AGGREGATIONS REPRESENT UNCRUSHED AGGLOMERATES OF ALUMINA WHICH CAN PRODUCE FLAWS IN THE FINISHED MATERIAL

Baboon Implant Studies

Animal implant procedures have been performed in the adult female baboon. Following extraction, the mandibular tooth socket, either molar or pre-molar, is shaped using a bone burr. A socket is formed by a continual fitting procedure. The root is firmly tapped into the alveolar bone until the first serration is into bone. The roots are given no further attention, except administration of prophylactic antibiotics immediately post surgery and a soft diet for two weeks. The roots are observed periodically for three months. Radiographic examination and manual palpation indicate if the root is adequately stable for reconstruction. A similar procedure has been used to implant roots in edentulous sites.

Restoration of the implants is facilitated by prefabrication of a gold post and core prior to implantation. Following adequate stabilization by bone ingrowth into the serrations, the post and core is cemented into place. Impressions are taken. A gold crown is fabricated and cemented into place. Care is taken to provide correct occlusion. The implant is periodically examined and documented by radiographs and photographs.

Human Implant Procedures

Rectangular implants are placed in edentulous or fresh extraction sites in mandibular molar or premolar sites. Roots are placed in sites where they will function as single free standing implants when reconstructed. The roots are observed visually and radiographically on a periodic basis until rigidity via ingrowth is assured. As with the animal studies, a gold post and core was prefabricated for each implant. It is anticipated that reconstruction will be similar to the procedures used in animals. All clinical studies are performed at The Ohio State University College of Dentistry in compliance with a protocol approved by the University human subjects committee.

RESULTSAnimal Studies

During the last year, implants have been observed in the colony of nine baboons. The majority of these roots have been put into function. Again, as was observed last year, the failure rate has been low. Presently 31 roots are being followed in the baboons. Twenty-four of these roots have been reconstructed and are in function. Six roots are rigid and now await reconstruction. One failure was noted shortly after implant. This root never stabilized. A second root fractured after several months in function. The cause of the fracture is not known. This particular root was produced from lower strength alumina than that presently being used. The apical portion of this root is still firmly anchored in alveolar bone. A third root placed into function too soon (after 2 months) remains mobile. It has been mobile for 21 months. This root is being followed to assess the fate of mobile roots. The crown height has been reduced on this root to decrease its function. The root has not become inflamed nor is it mobile enough to allow easy removal. Bone ingrowth has been sufficient to provide retention. Apparently, mobility has promoted the generation of connective tissue. There does not appear to be a continued loss of alveolar bone. This implant is considered a failure by our classification.

Roots in function are considered "successful" by the following criteria:

- (1) Radiographic appearance of dense bone ingrowth into serrations
- (2) Resistance to movement by manual palpation (rigid)
- (3) Minimal gingival irritation
- (4) Maintenance of occlusion

Roots which have remained rigid but have not been put into function are termed "potentially successful" until they are reconstructed. All "successful" roots in this study were implanted a minimum of 3 months before reconstruction.

In the 9 animals being observed the following history of functional success has been observed:

Number of Roots	Time in function (months)
2	37 months
2	30 months
1	16 months
10	12 months
6	9 months
2	6 months
Total	23

When the two failed implants are considered, a total of 25 functional roots are now in study. The consequent failure rate to date is 2/25 or 8%. Since the failures occurred early in their functional history, "failure" rate appears to decrease with implant function time. All failures have been with elliptical roots.

An additional 6 roots are implanted, awaiting reconstruction. One additional root was implanted and lost shortly thereafter. Consequently a failure rate of 1/7 or 14% has been observed this year prior to reconstruction. As in previous years, the failure rate is greater immediately following implantation. Similar to last year (1977), the failure rate has remained at a low level when compared to our earlier studies. Prior to 1977 the failure rate during the first three months was approximately 40 percent. As before, the factors responsible for decreased failure appear to be (1) a greater selection of root sizes available to assure better initial fit - both rectangular and elliptical roots were available; (2) longer (12 mm) roots were used; and (3) a design to allow greater flexibility of vertical placement was incorporated.

Gingival irritation, however minimal, is a drawback of this implant in the baboon. The minor irritation appears to be related both to the approximation of gold to the gingival tissue as well as to the relatively poor oral hygiene of the baboon. Infection has never been a causative factor in the loss of an implant. Apparently, the environment in the oral cavity allows the implant to survive even though there is no attachment of gingiva to the ceramic root. The gingiva is histologically observed invading the uppermost serration. In the majority of these implants, attachment of gingiva to the surrounding alveolar bone has been maintained.

Figure 3 shows two implants in function for 37 months. These implants are still functional and successful by the indicated criteria. Figure 4 shows a radiograph for the same implants as shown in Figure 3. Ingrowth of bone and the maintenance of that bone is apparent.

Figure 5 is a pair of implants in function for 1 year. These implants are typical of implants in function for that time period. Figure 6 is a radiograph of the implants in Figure 5. These particular implants are rectangular roots 12mm long with 1.5mm deep serrations.

Clinical Studies

To date, implants have been placed in molar mandibular sites in 7 patients. The patients have been followed on a weekly basis for 4 months. As anticipated, the clinical course appears to be somewhat like the baboon, however slower. The roots appear rigid for the first month following implant. They then loosen slightly, as exhibited by manual palpation. Radiographically, more bone loss is seen at the human alveolar crest than is evident in baboons. In the second and third month increased density of bone about the implant can be noted. The stability of the root increases at the same time.

Gingival health (at the implant site) in all patients has been exceptionally good. No inflammation has been noted after a very short initial post-operative period. Post surgical pain perceived by the patients has been remarkably low in all cases. Patients generally comment that little or no pain is felt from the implant site. To date patients have remained pain free.

The longest implant time is approximately four months, and no roots are yet in function. Consequently, success or failure claims are premature. To date no counterindications have been noted. Implantation of patients is continuing until an initial group of 25 is complete.

Figure 7 shows a human implant prior to reconstruction. Gingival health surrounding the implant appears excellent. The stabilization process is slower than that observed in baboons. Figure 8 is a radiograph of the implant seen in Figure 7, 2 months post implant. Note that the implant is two serrations (3mm) longer than the baboon implants.

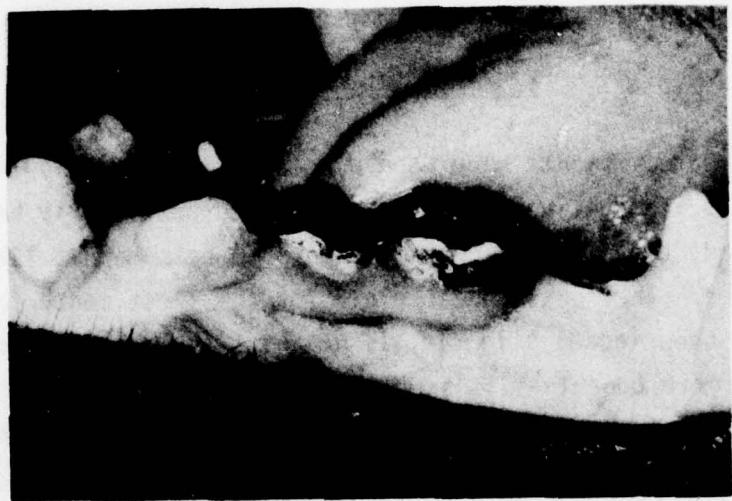


FIGURE 3. PHOTOGRAPH OF ALUMINA IMPLANTS IN FUNCTION
FOR 37 MONTHS IN THE BABOON

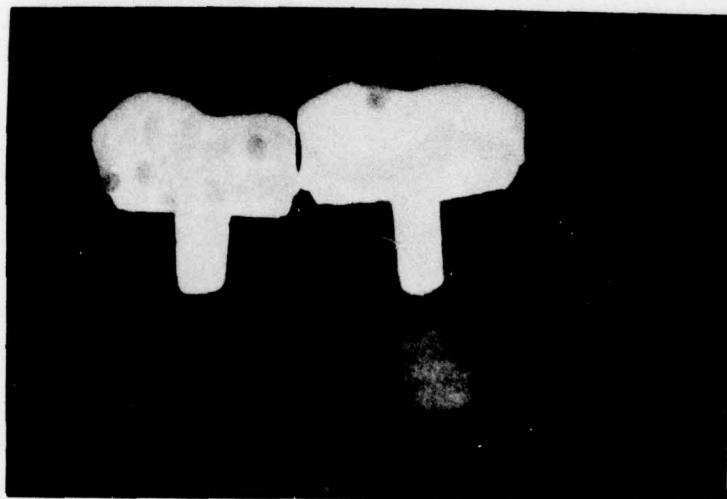


FIGURE 4. RADIOGRAPH OF IMPLANTS IN FUNCTION FOR
37 MONTHS IN THE BABOON



FIGURE 5. PHOTOGRAPH OF IMPLANTS IN FUNCTION
FOR 1 YEAR IN THE BABOON

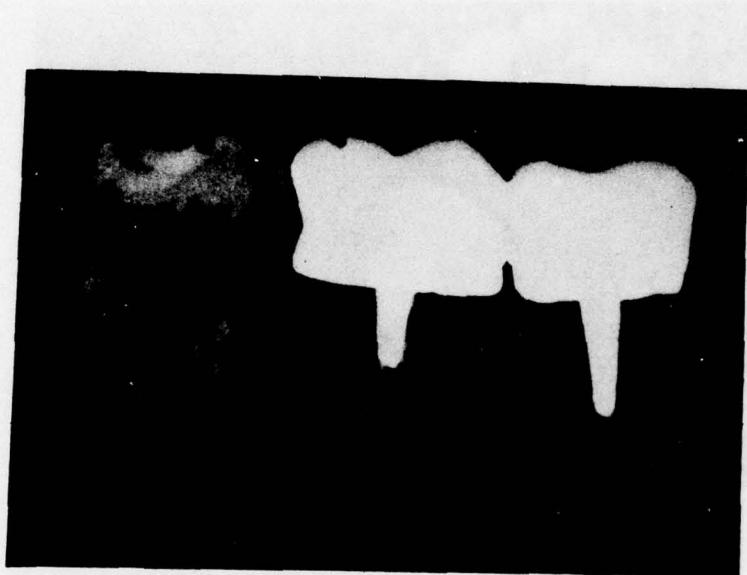


FIGURE 6. RADIOGRAPH OF IMPLANTS IN FUNCTION
FOR 1 YEAR IN THE BABOON

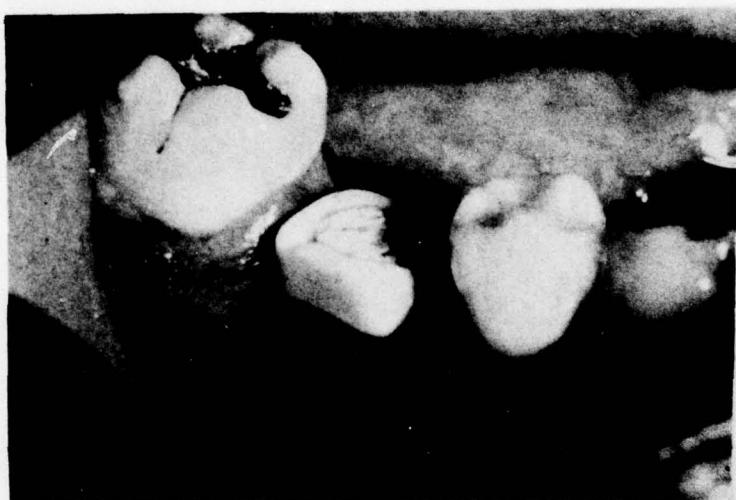


FIGURE 7. PHOTOGRAPH OF HUMAN IMPLANT IN PLACE FOR
2 MONTHS, AWAITING RECONSTRUCTION

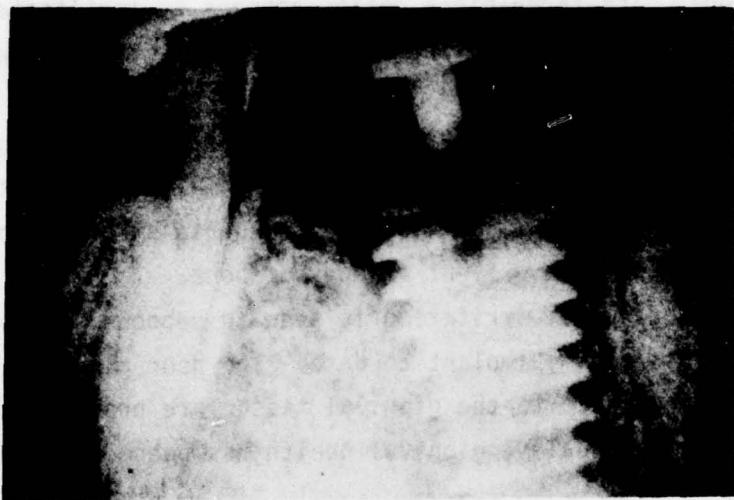


FIGURE 8. RADIOGRAPH OF HUMAN IMPLANT IN PLACE FOR TWO MONTHS

CONCLUSIONS AND RECOMMENDATIONS

The research progress to date continues to indicate a high probability of success for the serrated, 3-piece tooth root designed in our laboratory. The failure rates continue low as periods of function reach the 3-year point in baboons. The high degree of success still appears dependant upon the success of an initial ingrowth period during which the bone closely approximates the implant and rigidly fixes the relation between alveolar bone and implant. The three-piece design appears to facilitate the rigidizing process by providing an environment of minimal stress in which hard tissue can be formed.

Once the hard tissue has ingrown, the serration design appears to provide adequate stress distribution so that normal occlusal stresses do not produce resorption of bone. Additionally, adequate stresses appear to be placed upon the implant to prevent atrophy of bone.

Minimal gingival irritation is seen in baboons. This drawback has not led to the loss of any implant to date. The poor gingival health and/or the approximation of gold to the gingival tissue are probable causes of this irritation. Clinically, gingival health has been excellent in all cases.

The clinical experience with this implant is still limited. Consequently, no conclusion should be drawn regarding its success. To date, there is nothing to discourage our enthusiasm.

The method of computer grinding implants from bisque-fired alumina continues to be a flexible and practical method of producing these implants. This particular machining sequence used provides a very high strength and quality implant. Bending tests, as well as visual and radiographic examination of fired alumina specimens and roots have been utilized to provide quality control for the roots. Of these techniques, radiography appears to be the least useful. The failure mode of alumina appears to be initiated from porosities not completely closed during the firing to full density. Hence, any method to further reduce porosity will improve root quality.

The long-term animal implants should be continued for as long as it is practical. The valuable data being collected from these animals

will probably never be available from a human study. The animal colony provides a captive, relatively uniform population which can be examined at will. Additionally, the animal population will provide histology samples and pathology data at necropsy. Other implant sites are potentially available in these animals to investigate further design modifications. The human implant study should be continued to provide the ultimate answer as to the success of the implant. The method of root production presently being utilized is desirable for research purposes and should be continued. Major emphasis in root production should be placed on assuring high quality implants for experimentation.

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